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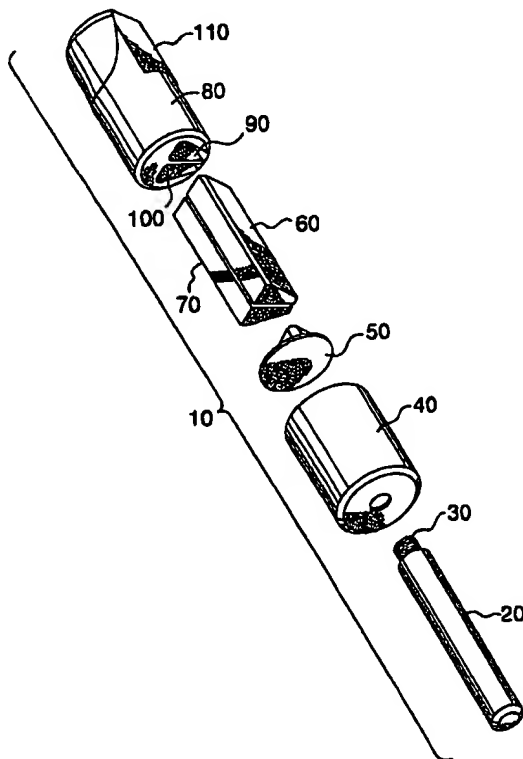
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(54) Title: DEVICE FOR VERIFYING THE ACCURACY OF A SPECTRAL ANALYZER



(57) Abstract: The present invention provides an artificial member (80, 210), which mimics the absorbance spectrum of a body part and includes the spectral components of blood analytes. The artificial member comprises a light scattering and reflecting material, and has a chamber portion comprising one or more chambers (90, 100, 220). The artificial member is configured to be reproducibly received in a measuring receptor which receptor is operatively connected to a non-invasive monitoring device.

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DEVICE FOR VERIFYING THE ACCURACY OF A SPECTRAL ANALYZER

FIELD OF INVENTION

5 This invention is in the field of non-invasive spectral analysis of analytes in tissues and relates more particularly to a device which may be used with a non-invasive monitoring system used for determining concentrations of various blood components.

BACKGROUND OF INVENTION

10 Non-invasive devices exist which are used externally to measure either the concentration of the constituent in gases admitted by the body or the concentrations contained in a patient's body part, typically a finger. United States 5,429,128 describes a finger receptor which receives a finger of a user and is for use with a non-invasive
15 monitoring device. United States 5,361,758 describes such a monitoring device.

 During the course of using a monitoring device which is operatively coupled to a finger receptor, many uses of the receptor and the monitoring device will with time result in variations in readings
20 due to internal drift and other variable aspects of such monitoring devices. Accordingly, it is desirable to have a means to rapidly and easily check the precision and accuracy of such a monitoring device.

SUMMARY OF THE INVENTION

 The present inventors have developed a device shaped to fit a
25 receptor which is operatively connected to a non-invasive monitoring device, which device is useful in monitoring the precision and accuracy of the non-invasive monitoring device and which permits photometric correction of the instrument.

 In its broad aspect the invention provides a method and a device
30 made of materials for carrying out the method which reproduce absorption spectra associated with various body parts when such parts are subjected to spectral determination. A device according to the present invention is made of a material that exhibits the same light scattering and absorbance characteristics as a body part, preferably of
35 an earlobe, lip, fold of skin or finger, most preferably, a finger.

 According to one embodiment of the present invention there is provided an artificial member, which mimics the absorbance spectrum

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of a body part and includes the spectral components of blood analytes. comprising a light scattering and reflecting material, which member has a chamber portion comprising one or more chambers, said member configured to be reproducibly received in a measuring
5 receptor which receptor is operatively connected to a non-invasive monitoring device, preferably the body part which is mimicked is a finger. In one embodiment there is one chamber, while in another there are two chambers.

In another embodiment each chamber is filled with an O-
10 cellulose material which mimics light scattering properties of tissue, preferably each chamber is filled with a gel material containing Amaranth and sodium benzoate and holding light scattering and reflective particles which mimic the light scattering properties of tissue. In another embodiment the material which fills each chamber is fluid
15 free. In yet another embodiment the reflective particles comprise Teflon-PTFE, Titanium Dioxide (TiO₂) or are Polystyrene nanospheres.

In yet another embodiment the light scattering and reflecting material of the member is Teflon-PTFE, preferably the configuration of the member where in the configuration of the member to be
20 reproducibly received, comprises a stabilizing member extending from the chamber portion to reversibly urge other surfaces of the member into contact with the measuring receptor, preferably the stabilizing member is as depicted in Figure 9.

In another aspect according to the present invention there is
25 provided a method of transferring algorithms from one spectral instrument to another comprising the steps of:

measuring a spectral response of a member in a first spectral instrument;

measuring a spectral response of the member in a second
30 spectral instrument; determining any difference in measurements from the first instruments and second instrument; and

modifying the algorithms of the instruments to account for any difference, wherein the member of the method mimics the absorbance spectrum of a body part and includes the spectral components of blood
35 analytes. comprising a light scattering and reflecting material, which member has a chamber portion comprising one or more chambers,

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said member configured to be reproducibly received in a measuring receptor which receptor is operatively connected to a non-invasive monitoring device, preferably the body part which is mimicked is a finger. In one embodiment of the method there is one chamber, while
5 in another there are two chambers.

In another embodiment of the method each chamber is filled with an O-cellulose material which mimics light scattering properties of tissue, preferably each chamber is filled with a gel material containing
10 Amaranth and sodium benzoate and holding light scattering and reflective particles which mimic the light scattering properties of tissue. In another embodiment the material which fills each chamber is fluid free. In yet another embodiment the reflective particles comprise Teflon-PTFE, Titanium Dioxide (TiO₂) or are Polystyrene nanospheres.

In yet another embodiment of the method the light scattering and reflecting material of the member is Teflon-PTFE, preferably the
15 configuration of the member where in the configuration of the member to be reproducibly received, comprises a stabilizing member extending from the chamber portion to reversibly urge other surfaces of the member into contact with the measuring receptor, preferably
20 the stabilizing member is as depicted in Figure 9.

The invention in another embodiment provides a method for mimicking the absorbance spectrum of a body part which includes the spectral components of blood analytes. comprises inserting a member
25 in a measuring device which is operatively connected to a non-invasive monitoring device; taking measurements with the device and comparing the results with those obtained from a body part of a subject which the member is intended to mimic, wherein the member is comprised of a light scattering and reflecting material, which member has a chamber portion comprising one or more chambers,
30 and the member is configured to be reproducibly received in the measuring receptor.

According to one embodiment of this method the member of the method mimics the absorbance spectrum of a body part and includes the spectral components of blood analytes. comprising a light
35 scattering and reflecting material, which member has a chamber portion comprising one or more chambers, said member configured to

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be reproducibly received in a measuring receptor which receptor is operatively connected to a non-invasive monitoring device, preferably the body part which is mimicked is a finger. In one embodiment of the method there is one chamber, while in another there are two chambers.

In another embodiment of the method each chamber is filled with an O-cellulose material which mimics light scattering properties of tissue, preferably each chamber is filled with a gel material containing Amaranth and sodium benzoate and holding light scattering and reflective particles which mimic the light scattering properties of tissue. In another embodiment the material which fills each chamber is fluid free. In yet another embodiment the reflective particles comprise Teflon-PTFE, Titanium Dioxide (TiO₂) or are Polystyrene nanospheres.

In yet another embodiment of the method the light scattering and reflecting material of the member is Teflon-PTFE, preferably the configuration of the member where in the configuration of the member to be reproducibly received, comprises a stabilizing member extending from the chamber portion to reversibly urge other surfaces of the member into contact with the measuring receptor, preferably the stabilizing member is as depicted in Figure 9.

Other features and advantages of the present invention will become apparent from the following detailed description. It should be understood, however, that the detailed description and the specific examples while indicating preferred embodiments of the invention are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in relation to the drawings in which:

Figure 1 shows absorbance spectra from 500-1380 nm for globulins, glucose, urea, creatinine, cholesterol and human serum albumin with water displacement compensation.

Figure 2 shows 2013 absorbance spectra from 585-1100 nm for the finger from 32 subjects.

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Figure 3 shows absorbance spectra (580-1100 nm) for water in a subject's finger and an artificial member of the present invention.

5 Figure 4 shows absorbance spectra from 580-1100 nm for a subject's finger and an artificial member as shown in Figure 3 as well as the curve representing difference of the first two spectra.

Figure 5 is absorbance spectra from 580-1100 nm for water in a finger and in an artificial member of the invention where the member contains pink sponge (SCOTCH BRIGHT™) and water.

10 Figure 6 is absorbance spectra from 580-1100 nm for water in a finger and in an artificial member of the invention where the member contains Polystyrene nanospheres in water and gelatin plus Amaranth and sodium benzoate as a preservative.

15 Figure 7 is an isometric exploded view of an artificial member according to the present invention in a configuration for use with a finger receptor.

Figure 8 is a side view of the member of Figure 7.

Figure 9 is an isometric exploded view of a further embodiment of an artificial member according to the present invention in a configuration for use with a finger receptor.

20 Figure 10 is a side view of the member of Figure 9.

Figure 11 is a side view of an assembled member of Figures 9 and 10.

DETAILED DESCRIPTION OF THE INVENTION

25 As used herein "concentration" or "concentration level" means the amount or quantity of a constituent in a solution whether the solution is in vitro or in vivo.

As used herein, "constituent" means a substance, or analyte found in a tissue and includes carbohydrates such as for example glucose, bilirubin, a protein, for examples albumin or , hemoglobin.

30 As used herein, "fluid free" means having no appreciable amount of liquid present,

35 As used herein, "tissue" means any tissue of the body of a subject including for example, blood, extracellular spaces, and can mean the entire composition of a body part such as a finger or ear lobe.

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As used herein "subject" means any member of the animal kingdom including, preferably, humans.

As stated above, the present inventors have prepared a device which is capable of insertion in a receptor which is used with a non-invasive monitoring device. The use of such a device or artificial member is to enable the user of such a non-invasive monitoring device to quickly and easily check the precision and accuracy of the non-invasive monitoring device.

Spectral data, obtained using a standard spectrophotometer and compensated for water displacement, were collected from in vitro measurement of a cuvette containing samples of various blood constituents and are illustrated in Figure 1. As may be seen, the spectra associated with the various constituents are complex. In contrast, the spectra for a living finger is relatively simple, particularly in the 500-1100 nm region. This may be seen in Figure 2. Measurements taken in this region are relatively consistent regardless of individual measurements or the individual being scanned. In this respect, the data presented in Figure 2 represent the combined spectra of 33 people for whom a total of 2,013 measurements were taken and are collectively presented. Accordingly, an artificial member must be able to provide a spectrum which is comparable to those presented in Figure 2 or the absorbance spectra of another body part. It will be appreciated that in order to develop a comparable artificial member, such member must mimic the situation of which light is directed to a body part. Light entering the body is scattered and that light which emerges and radiates in virtually every direction. Absorption begins at the point of which the light enters the tissue. In the case of transmission, as the light passes through the tissue, more and more light is absorbed as the path length increases. Clearly, if path length is too great, very little light is left for measurement and the absorbance calculations will be subject to considerable error due to noise. The considerations are also true in respect of the artificial member. Consequently, according to one embodiment of the present invention, it is the artificial member that will exhibit the same properties of light scattering, reflectivity and absorption as exhibited by a living human finger. Accordingly, an artificial member of the present invention is

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made of a highly reflective material such as, for example, teflon, in particular teflon-PTFE virgin material (where PTFE means polytetrafluoroethylene). In addition, to concurrently mimic scatter, which is derived from the interior of a living body part, the artificial member must show sufficient internal reflectance to achieve a comparable result. In this respect, a chamber, or container space exists in the member, although, depending on the body part being mimicked, reflective material may comprise part of the internal structure of the chamber of the member.

An artificial member must be capable of being easily inserted into and removed from a receptor which is used to measure spectral characteristics of constituents in a body part. In this respect, the shape of the artificial member will be determined by the shape of the receptor. In the case of a finger receptor, the artificial member must have corresponding shapes to ensure that there is a constant path length from the point at which light is delivered to the finger or artificial finger and the point at which light exists the finger or artificial body part.

It will be appreciated by those skilled in the art that an artificial member of the present invention is for use in association with any measuring receptor which is combined with any non-invasive monitoring device which is based on the principle of measuring the absorbance (or reflectance) of radiation passing through (or reflecting from) a body part. In this respect, such devices operate according to the Beer-Lambert law, namely that the concentration of constituents is proportional to a constant of proportionality (the extinction coefficient), the path length, and the absorbance ($\text{LOG}_{10} [1/T]$, where T is the transmittance, i.e., the proportion of light of a given wavelength that is transmitted through the matrix).

By measuring the absorbance at a number of predetermined wavelengths, some of which will control for path length, it is possible to calculate the concentration of a given constituent. The same principles of measurement which are applied to determining concentration of constituents in body parts with a non-invasive device are equally applicable to an artificial member of the present invention. Consequently, while water is a preferred constituent for measurement

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and accuracy testing with an artificial member, any other constituent, or constituents may be used. In this respect, it will be appreciated that the constituents will be preferably held in the member, preferably in the chamber or chambers of the member. In some applications it may be necessary to introduce other absorbing or reflecting material in the chamber or intermixed with the composition of the reflective material.

It should be noted that there are several ways in which absorbance measurements may be taken, and without limiting the scope of the applicability of the present invention, the two methods are: (1) use light from a scanning monochromator and pass it through a selected part of the body and collect the light transmitted through onto a silicon detector. A second measurement involves a measurement of the light transmitted in the absence of the body part. From these two measurements the transmittance, and hence the absorbance, may be calculated; (2) use a polychromatic light source, pass it through the body part to be measured, collect the light, collimate it onto a diffraction grating and focus the different wavelengths of light on a linear array detector. Each element of the array will then measure the intensity of light for a narrow band of wavelengths. A similar measurement in the absence of the body part (reference scan) will then allow computation of the transmittance for each element. Because the various elements of the array have slightly difference dark leakage currents, it is necessary to record a dark current and subtract it from both the sample scan and the reference scan before calculation of transmittance and absorbance.

There are several typical parts of the body from which measurements are made and these include the finger, the lip, the earlobe, a pinch of skin at the waist, the web between the thumb and forefinger, the web between toes. Accordingly, the present invention includes artificial members replicating each of these.

One of the problems encountered in measuring absorbance in tissue is the spectral variability from one instrument to another due to physical differences in light transmission and collection. Because the phantom finger is designed to minimize variability of spectral response and physical placement in the finger receptor, it can be used to quantify the spectral differences between instruments. With careful wavelength

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calibration, the difference in spectral response of the phantom finger between one instrument and another may be used to correct the spectrum of the second instrument to that of the first by adding the spectral difference to the second instrument. This is termed photometric correction and coupled with suitable wavelength accuracy, is the basis on which algorithms can be transferred from one instrument to another.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

We will now describe two non-limiting exemplary embodiments of the present invention. Firstly, referring to Figures 7 and 8, an artificial member according to the present invention is illustrated. In particular, the artificial member is intended to represent an artificial finger for use in association with a finger receptor which is operatively connected to a non-invasive monitoring device such as a spectrophotometer.

The artificial finger is comprised of a handle which may be prepared from aluminum or any other material which is rigid and has strength characteristics. The handle at 20 has a tip 30 which is used to connect the handle with a holding collar 40. The holding collar is used to provide a large grasping means as well as sealing cover for the highly reflective and light scattering portion of the artificial finger 80. The holding collar 30 is made of black plastic (DELRIN); however, any other minimally reflective or nonreflective plastic material is acceptable. The holding collar fits by means of an interference fit over the artificial member 80. The artificial member 80 is comprised of a material which provides a scattering effect similar to tissue such as the skin or a digit, namely Teflon-PTFE; however, any other material such as Fluorosint™ (DSM Engineering Plastic Products, Inc.) or Teflon-PTFE with 25% glass fibers which is capable of providing such a scattering effect is suitable. This member has a hollow or chamber-like portion which determines the amount of internal scattering based on the material filling the cavity. The exact dimensions of this chamber are selected to achieve a spectrum of absorption similar to that observed of a natural finger. More than one chamber may be used.

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According to a preferred embodiment the chamber as shown in Figure 7 is divided into two portions, 90 and 100, although similar results may be achieved with more chambers. The chambers 90 and 100 act as containers to hold water or any other solutions which are being used as part of the artificial member. Also placed in the artificial member for the purposes of replicating absorbance of a finger are O-cello materials commonly available as sponge (SCOTCH BRIGHT™) and which are shaped to fit into the containers 90 or 100. The chamber may also be filled with gel materials which hold light scattering materials such as Titanium Dioxide (TiO₂) or Polystyrene nanospheres.

A stopper made of rubber or other suitable material is fashioned to fit in to seal the top open end of containers 90 and 100 over which holder collar 40 is placed. These parts and their interrelationship is better seen in Figure 8 which provides a side view of the artificial finger and illustrates the components in place. The shaping of the artificial finger in order to provide an interface between the artificial member and the receptor thereby achieving a minimum of variability and maximum of repeatability whilst allowing for the passage of light through the artificial member thereby optimizing pathlength and its variability between measurements with the artificial member is seen in the isometric exploded view in Figure 6 as item 110. This shaping will vary from one artificial member to the other depending upon the receptor for which the artificial members created and depending upon the device in which the artificial member is being used to verify the accuracy of the spectral analyzer.

Referring now to Figures 9 10, and 11, another embodiment of an artificial member according to the present invention is illustrated. In particular, this artificial member is also intended to represent an artificial finger for use in association with a finger receptor which is operatively connected to a non-invasive monitoring device such as a spectrophotometer.

The artificial finger (200) of Figures 9, 10, and 11 is comprised of a handle, which may be prepared from aluminum or any other material,

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which is rigid and has strength characteristics. The handle at 290 has a tip 300, which is used to connect the handle to the artificial member 210 at 230. The artificial member is comprised of a material which provides a scattering effect similar to tissue such as the skin or a digit, namely

5 Teflon-PTFE; however, any other material such as Fluorosint™ or Teflon-PTFE with 25% glass fibers which is capable of providing such a scattering effect is suitable. This member has a hollow or chamber-like portion 220, which determines the amount of internal scattering based on the material filling the cavity. The exact dimensions of

10 this chamber are selected to achieve a spectrum of absorption similar to that observed of a natural finger. More than one chamber may be used. The chamber 220 acts as container to hold water or any other solutions which are being used as part of the artificial member 210. Also placed in the artificial member for the purposes of replicating

15 absorbance of a finger are O-cell-o materials commonly available as sponge 260 (SCOTCH BRIGHT™) and which is shaped to fit into the container 220. The chamber 220 may also be filled with gel materials, which hold light scattering materials such as Titanium Dioxide (TiO₂) or Polystyrene nanospheres. A stopper 270 made of rubber or other

20 suitable material is fashioned to fit in to seal the top open end of the chamber 220. The stopper 270 maybe inserted or removed by gripping the stub 280 provided for this purpose. A plunger, or "stabilizing member" 240 made of 303 Stainless Steel or other material which is rigid and has strength characteristics is press fit into the top of the

25 artificial member into mating cavity 250 and is held in place by an interference fit between the two parts. The purpose of the interlocking plunger 240 is to provide exact placement and holding of the artificial member when inserted into a finger receptor which is operatively connected to a non-invasive monitoring device. The stabilizing

30 member 240 when the artificial member is inserted into the finger receptor mates with a corresponding hole precisely placed in the finger receptor for this purpose, resulting in accurate placement of the artificial member 210 each time it is inserted into the finger receptor.

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These parts and their interrelationship is better seen in Figure 11 which provides a side view of the artificial finger and illustrates the components in place.

The following non-limiting examples are illustrative of the present invention.

EXAMPLES

Example 1

An artificial finger made of Teflon-PTFE was prepared, although as just stated any other highly reflective and light scattering material can be used. The artificial finger has a hollow portion containing within a further reflective surface, also made of Teflon-PTFE. When filled with water, the artificial finger provides a spectrum somewhat similar to that observed in a normal finger (see Figure 3). However, the peak of high absorbance found in the 580 nm region for a normal finger is noticeably missing. Indeed, the different aspects of the artificial finger and a normal finger are illustrated in Figure 4. As may be seen the only significant difference resides in the portion of the spectrum peak in the 580 nm region. To overcome the deficiency of the absorption spectra, various materials were tried; however, the inventors have determined that sponge pads (e.g. SCOTCH BRIGHT™) or other similar material is capable of providing an absorption spectrum like that of Amaranth which is comparable to absorption in a normal human finger. This may be seen most clearly in Figure 5. This artificial finger can be used to check the performance of any non-invasive monitoring device which is used to monitor the concentrations of various components of a subject's body parts.

Example 2

An artificial finger made of Teflon-PTFE was prepared, although as just stated any other highly reflective and light scattering material can be used. The artificial finger has a hollow portion containing within a further reflective surface, also made of Teflon-PTFE. When filled with water, the artificial finger provides a spectrum somewhat similar to that observed in a normal finger (see Figure 3). However, the peak of high absorbance found in the 580 nm region for a normal finger is noticeably missing. Indeed, the different aspects of the artificial finger

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and a normal finger are illustrated in Figure 4. As may be seen the only significant difference resides in the portion of the spectrum peak in the 580 nm region. To overcome the deficiency of the absorption spectra, various materials were tried; however, the inventors have determined that sponge pads (e.g. SCOTCH BRIGHT™) or other similar material is capable of providing an absorption spectrum like that of Amaranth which is comparable to absorption in a normal human finger. This may be seen most clearly in Figure 5.

An artificial finger made of Teflon-PTFE was prepared, and as just stated any other highly reflective and light scattering material can be used. The artificial finger has a hollow portion containing within a further reflective surface, also made of Teflon-PTFE. As just described, when filled with water, the artificial finger provides a spectrum somewhat similar to that observed in a normal finger, and the only significant difference resides in the portion of the spectrum peak in the 580 nm region. To overcome the deficiency of the absorption spectra nanospheres of polystyrene in water and gelatin plus Amaranth and sodium benzoate as a preservative were used. The results are illustrated in Figure 6.

As is readily apparent from the foregoing, this artificial finger can be used to check the performance of any non-invasive monitoring device which is used to monitor the concentrations of various components of a subject's body parts.

While the present invention has been described with reference to what are presently considered to be preferred examples, it is to be understood that the invention is not limited to the disclosed examples. To the contrary, the invention is intended to cover various modifications and equivalents included within the spirit and scope of the appended claims.

All publications, patents and patent applications referred to herein are incorporated by reference in their entirety to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated by reference in its entirety.

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WE CLAIM:

1. An artificial member, which mimics the absorbance spectrum of a body part and includes the spectral components of blood analytes, the artificial member comprising a light scattering and reflecting material, and having a chamber portion comprising one or more chambers, said member being configured to be reproducibly received in a measuring receptor which receptor is operatively connected to a non-invasive monitoring device.
2. The member according to claim 1 wherein the body part which is mimicked is a finger.
3. The member according to claim 1 or 2 wherein there is one chamber.
4. The member according to claim 1 or 2 wherein there are two chambers.
5. The member according to claim 1, 2, 3 or 4 wherein each chamber is filled with an O-cellulose material which mimics light scattering properties of tissue.
6. The member according to claim 1, 2, 3 or 4 wherein each chamber is filled with a gel material containing Amaranth and sodium benzoate and holding light scattering and reflective particles which mimic the light scattering properties of tissue.
7. The member according to claim 6 wherein the material which fills each chamber is fluid free.
8. The member according to claim 6 wherein the reflective particles comprise Teflon-PTFE, Titanium Dioxide (TiO₂) or are Polystyrene nanospheres.

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9. The member according to any one of claims 1-8 wherein the light scattering and reflecting material is Teflon-PTFE.

5 10. The member according to anyone of claims 1-9 where in the configuration of the member to be reproducibly received comprises a stabilizing member extending from the chamber portion to reversibly urge other surfaces of the member into contact with the measuring receptor.

10 11. The member according to claim 10 wherein the stabilizing member is as depicted in Figure 9.

12. A method of transferring algorithms from one spectral instrument to another comprising the steps of:

15 measuring a spectral response of a member according to claim 1 in a first spectral instrument;

measuring a spectral response of the member in a second spectral instrument; determining any difference in measurements from the first instruments and second instrument; and

20 modifying the algorithms of the instruments to account for any difference.

13. The method according to claim 12 wherein the body part which is mimicked by the member is a finger.

25 14. The method according to claim 12 or 13 wherein there is one chamber.

15. The method according to claim 12 or 13 wherein there are two chambers.

30 16. The method according to any one of claims 12-15 wherein each chamber is filled with an O-cellulose material which mimics light scattering properties of tissue.

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17. The method according to anyone of claims 12-15 wherein each chamber is filled with a gel material containing Amaranth and sodium benzoate and holding light scattering and reflective particles which mimic the light scattering properties of tissue.

18. The method according to claim 17 wherein the material which fills each chamber is fluid free.

19. The method according to claim 17 wherein the reflective particles comprise Teflon-PTFE, Titanium Dioxide (TiO₂) or are Polystyrene nanospheres.

20. The method according to any one of claims 12-19 wherein the light scattering and reflecting material is Teflon-PTFE.

21. The method according to anyone of claims 12-20 where in the configuration of the member to be reproducibly received comprises a stabilizing member extending from the chamber portion to reversibly urge other surfaces of the member into contact with the measuring receptor.

22. The method according to claim 21 wherein the stabilizing member is as depicted in Figure 9.

23. A method for mimicing the absorbance spectrum of a body part which includes the spectral components of blood analytes, the method comprising: providing a member that comprises of a light scattering and reflecting material, a chamber portion comprising one or more chambers, and a member configuration to be reproducibly received in a measuring receptor; inserting a member into a measuring device which is operatively connected to a non-invasive monitoring device; taking measurements with the device and comparing the results with those obtained from a body part of a subject which the member is intended to mimic.

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24. The method according to claim 23 wherein the body part which is mimicked by the member is a finger.

5 25. The method according to claim 23 or 24 wherein there is one chamber.

26. The method according to claim 23 or 24 wherein there are two chambers.

10 27. The method according to any one of claims 23-26 wherein each chamber is filled with an O-cellulose material which mimics light scattering properties of tissue.

15 28. The method according to anyone of claims 23-26 wherein each chamber is filled with a gel material containing Amaranth and sodium benzoate and holding light scattering and reflective particles which mimic the light scattering properties of tissue.

20 29. The method according to claim 28 wherein the material which fills each chamber is fluid free.

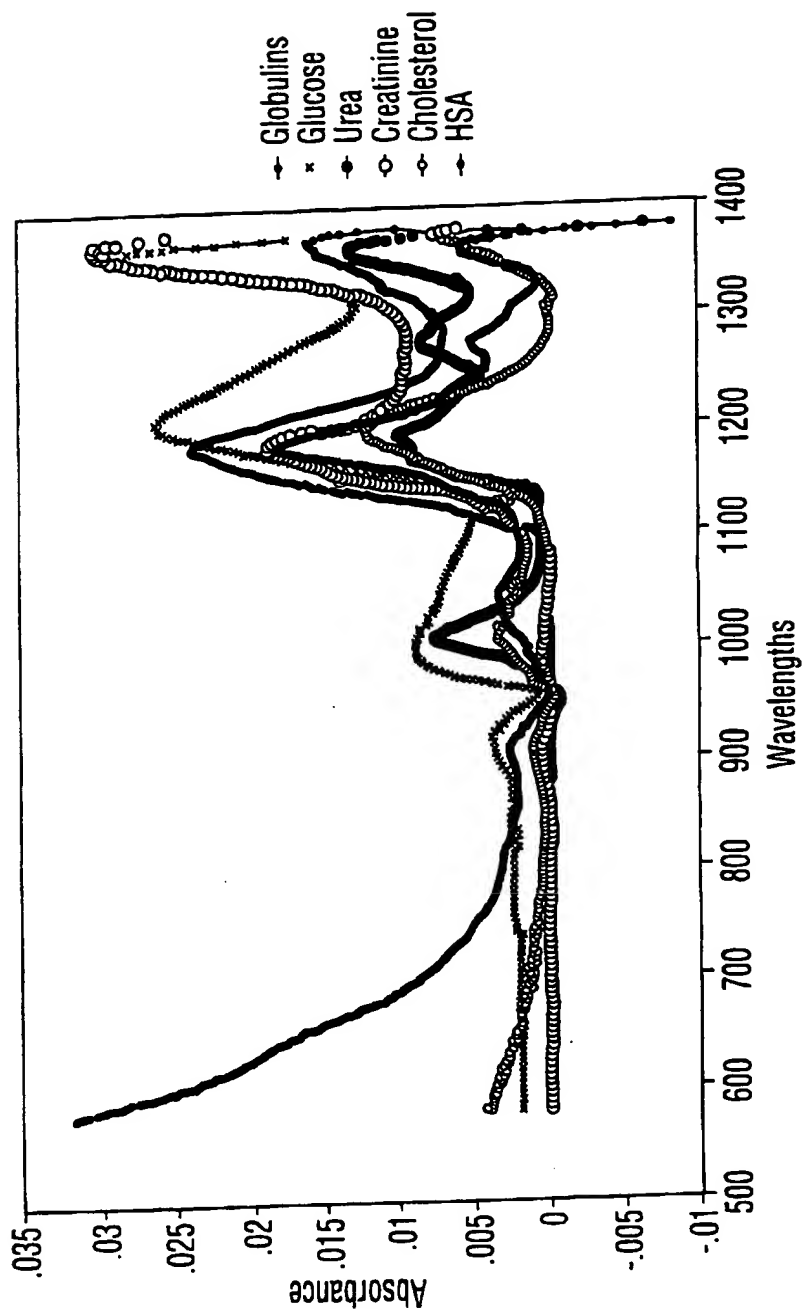
25 30. The method according to claim 28 wherein the reflective particles comprise Teflon-PTFE, Titanium Dioxide (TiO₂) or are Polystyrene nanospheres.

31. The method according to any one of claims 23-30 wherein the light scattering and reflecting material is Teflon-PTFE.

30 32. The method according to anyone of claims 23-31 where in the configuration of the member to be reproducibly received comprises a stabilizing member extending from the chamber portion to reversibly urge other surfaces of the member into contact with the measuring receptor.

35 33. The method according to claim 32 wherein the stabilizing member is as depicted in Figure 9.

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**FIGURE 1**

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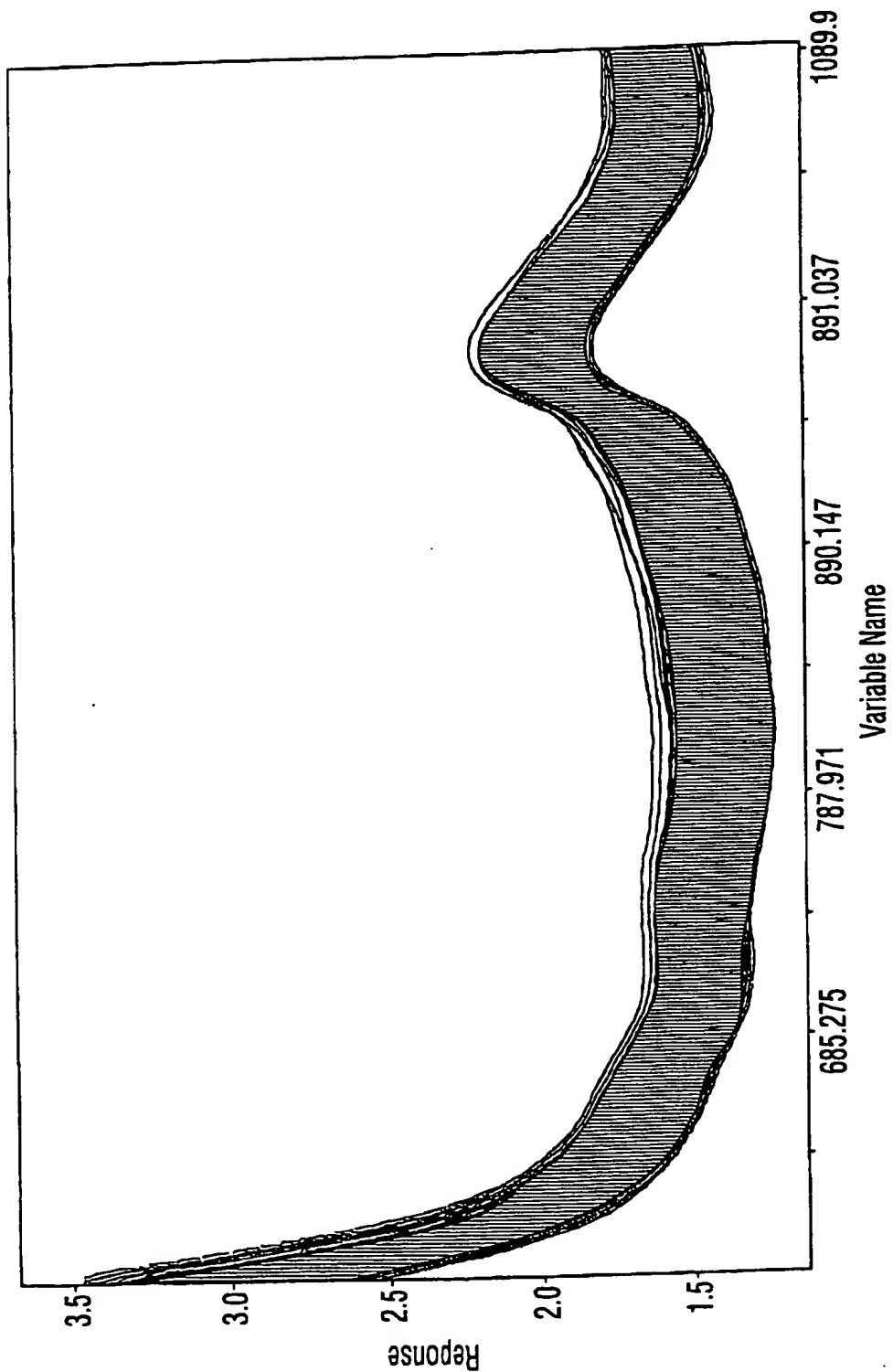
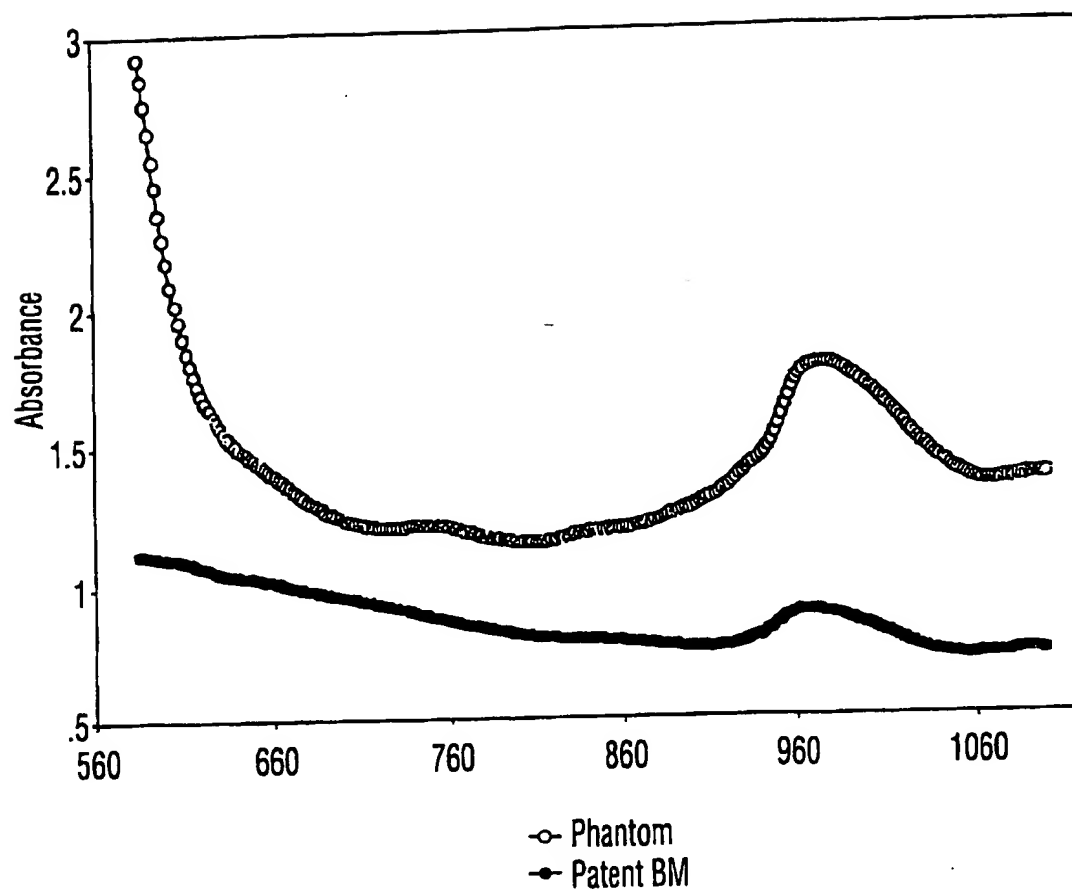
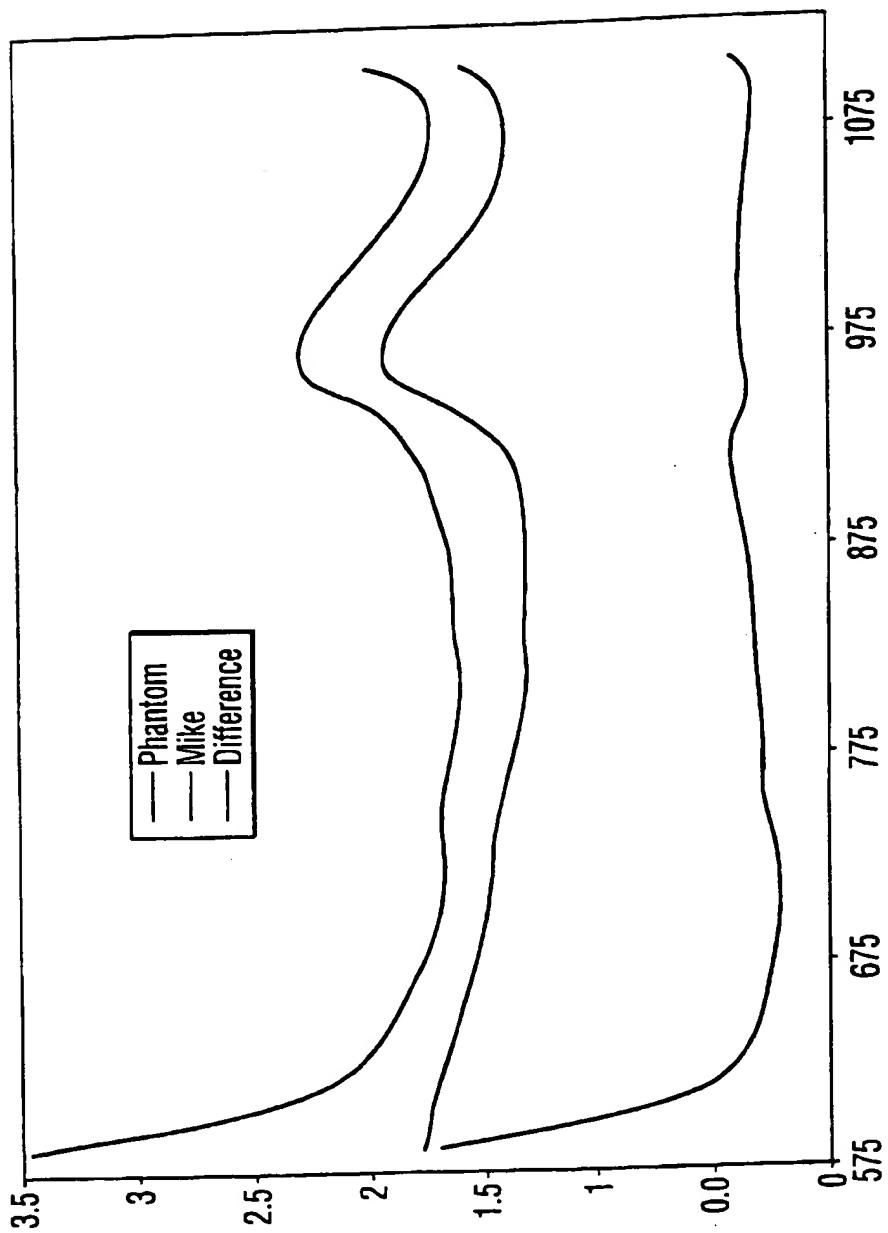


FIGURE 2

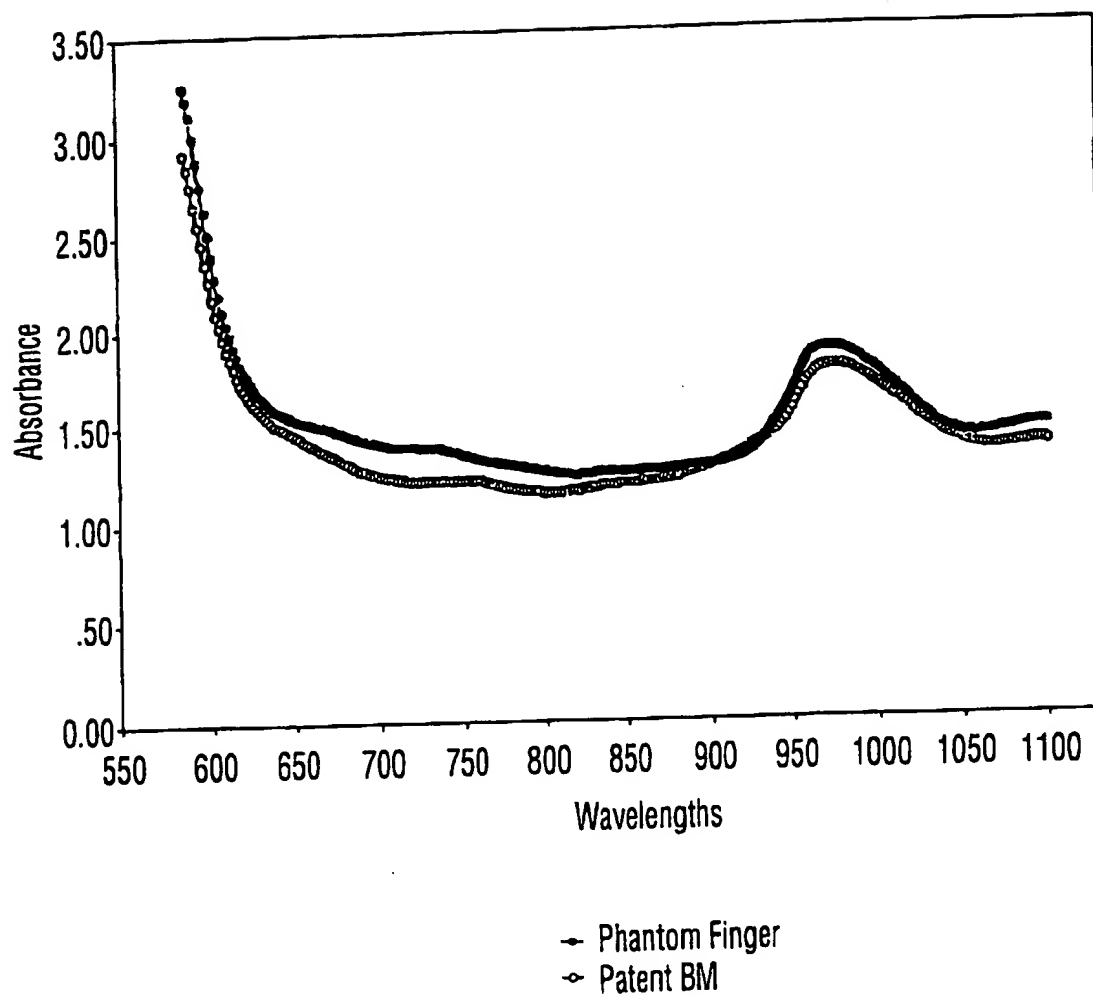
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**FIGURE 3**

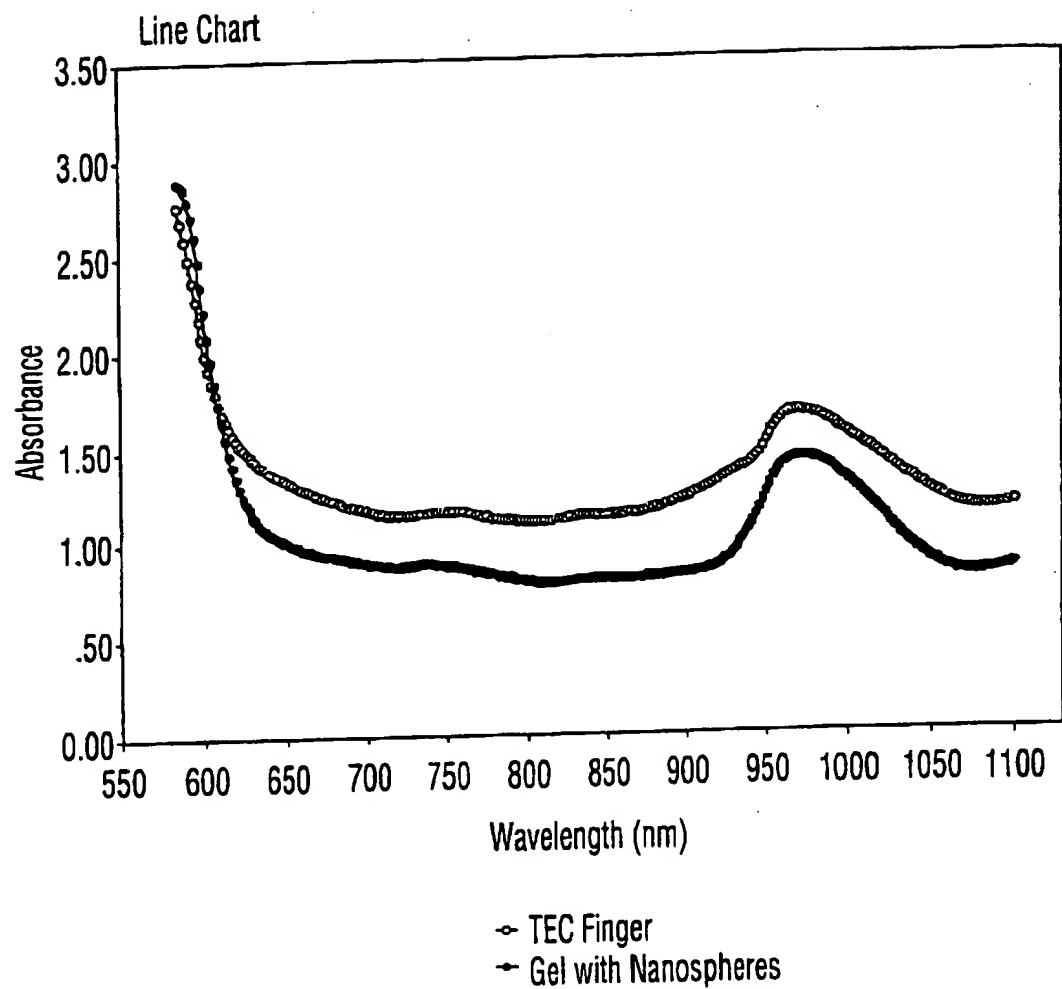
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**FIGURE 4**

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**FIGURE 5**

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**FIGURE 6**

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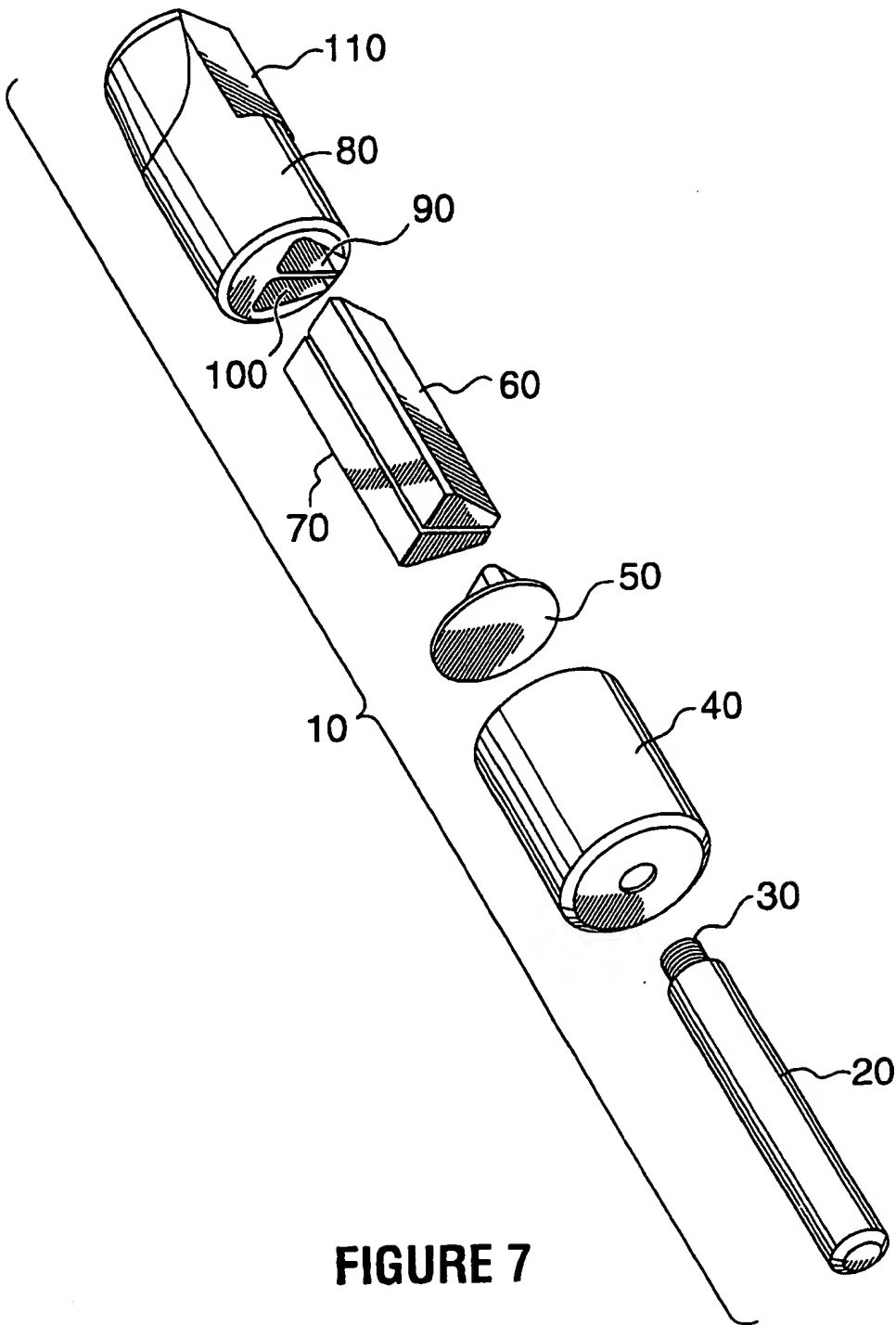


FIGURE 7

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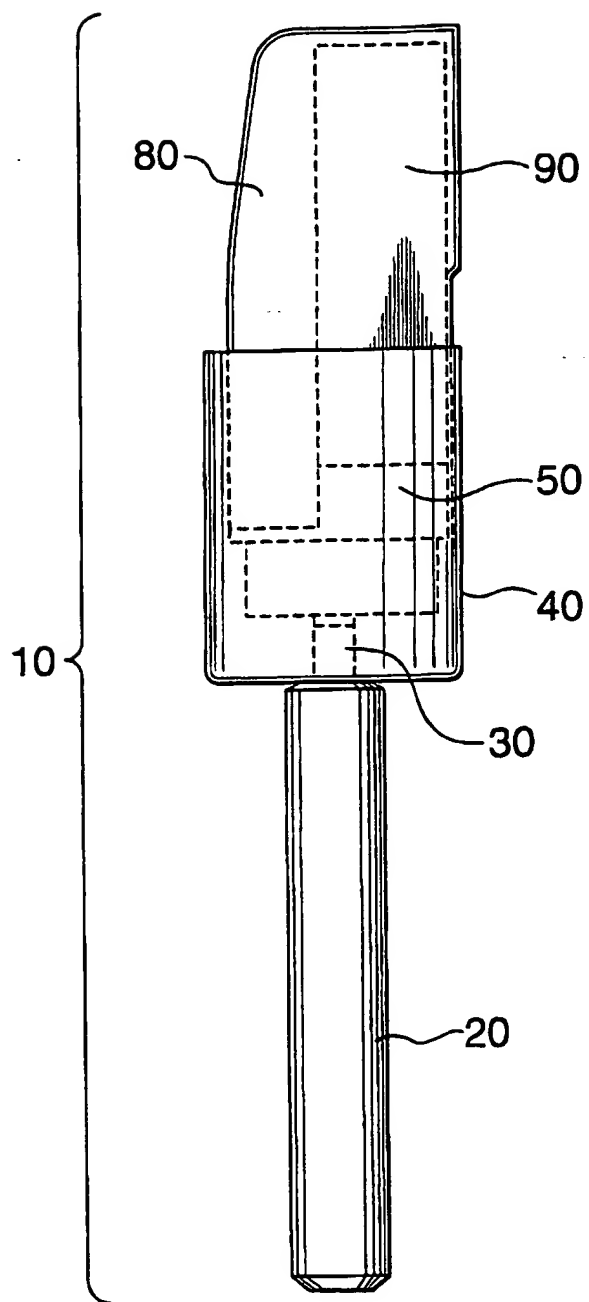


FIGURE 8

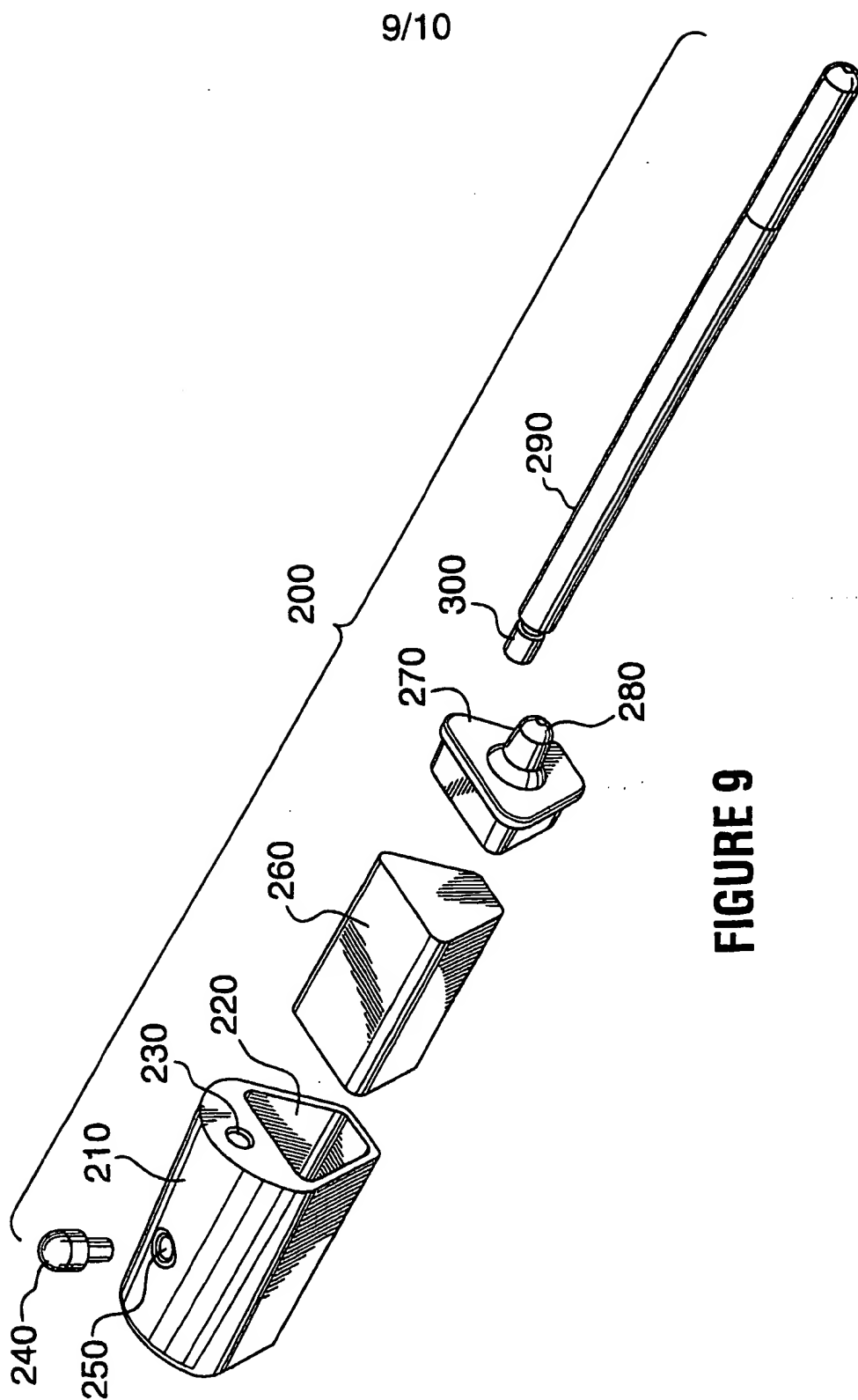


FIGURE 9

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